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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,871	10/11/2006	Yasumichi Fukuda	2006_1305A	1343
513 7590 08/22/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	
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			08/22/2008 PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/590,871

**Applicant(s)**

FUKUDA ET AL.

**Examiner**

Laura L. Stockton, Ph.D.

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 6, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-850)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date See Continuation Sheet

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :February 20, 2008 and February 29, 2008.

Art Unit: 1626

**DETAILED ACTION**

**Claims 1, 6, 8 and 9 are pending in the application.**

***Election/Restrictions***

Applicant's election of Group I {Claims 1-9 - drawn to products of formula (1) wherein X is CH<sub>2</sub>, CHF, CF<sub>2</sub> or CHOH} in the reply filed on November 16, 2007 was acknowledged in the previous Office Action. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Art Unit: 1626

Subject matter not embraced by elected Group I is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 16, 2007.

Currently amended claims 8 and 9 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the process for using the product as claimed can be practiced with another materially different product. For example, Pioglitazone and AVANDARYL<sup>TM</sup> are currently sold on the market for the treatment of diabetes.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Art Unit: 1626

Accordingly, claims 8 and 9 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Information Disclosure Statement***

The Examiner has considered the Information Disclosure Statements filed on February 20, 2008 and February 29, 2008.

The objection to the amendment filed August 28, 2006 under 35 U.S.C. 132(a) is withdrawn. Rejections and objections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the claims. Therefore, arguments pertaining to these rejections and objections will not be addressed.

Art Unit: 1626

Applicant's arguments concerning the unexpected results of the instant claimed invention over the prior art has been considered. However, the showing was not properly presented in a Declaration under 35 CFR 1.132.

Applicant's arguments with respect to claims 1 and 6 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1626

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haffner et al. {WO 2003/002553} in view of Villhauer {WO 98/19998}.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicant claims pyrrolidine compounds. Haffner et al. {see entire document; particularly formula (III) on pages 7, 13 and 22-27; and especially Example 18 on page 83} teach pyrrolidine compounds, which are structurally similar to the instant claimed compounds, that inhibit dipeptidyl peptidases.

***Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)***

The difference between the compounds of Haffner et al. and the compounds instantly claimed is that Haffner et al. teach a mono-cycloalkyl substituted with an alkyl versus a bicycloalkyl substituted with a methyl as instantly claimed.



Art Unit: 1626

***Finding of prima facie obviousness--rational and motivation (MPEP  
§2142-2413)***

However, Villhauer (see entire document; particularly pages 2-4; and especially Compound 29 on page 12) teach the interchangeability of a mono-cycloalkyl (page 2, definition b) and a bicycloalkyl (page 3, definition g) at the same position in compounds that inhibit dipeptidyl peptidases.

One skilled in the art would thus be motivated to prepare products embraced by Haffner et al. in view of the teachings of Villhauer, to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would inhibit dipeptidyl peptidases and be useful in treating, for example, arthritis. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Art Unit: 1626

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1626

This application contains claims 8 and 9 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1626

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/  
Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

August 23, 2008